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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,400	06/27/2003	Michael J. Pugia	MSA-3453	7945
7590	12/10/2004		EXAMINER	
Elizabeth A. Levy Bayer HealthCare LLC 63 North Street Medfield, MA 02052			SINES, BRIAN J	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/608,400	PUGIA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-26 are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 – 16, drawn to a microfluidic device and a method of using the device, classified in class 422, subclass 100.
- II. Claims 17 – 20, drawn to a microfluidic device, classified in class 422, subclass 82.
- III. Claims 21 – 23, drawn to a microfluidic device, classified in class 422, subclass 68.1.
- IV. Claims 24 – 26, drawn to a microfluidic device, classified in class 422, subclass 68.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these different inventions have different modes of operation. For example, the microfluidic device utilized in the invention of group I, as recited in claims 1 and 9, does not specifically require a capillary passageway or metering capillary, as required for the microfluidic device of group II, as recited in claim 17. Therefore, the microfluidic device utilized in the invention of group I can function using a different mode of operation, which does not require a capillary passageway or metering capillary.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these different inventions have different modes of operation. For example, the microfluidic device utilized in the invention of group I, as recited in claims 1 and 9, does not specifically require an adsorbent substrate strip as required for the microfluidic device of group III, as recited in claim 21. Therefore, the microfluidic device utilized in the invention of group I can function using a different mode of operation, which does not require an adsorbent strip.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these different inventions have different modes of operation. For example, the microfluidic device utilized in the invention of group I, as recited in claims 1 and 9, does not specifically require an inlet passageway containing ridges or grooves disposed perpendicularly to the sample flow and wherein the passageway widens into a reagent chamber, as required for the microfluidic device of group IV, as recited in claim 24. Therefore, the microfluidic device utilized in the invention of group I can function using a different mode of operation, which does not require an inlet passageway containing ridges or grooves disposed perpendicularly to the sample flow and wherein the passageway widens into a reagent chamber.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these

different inventions have different modes of operation. For example, the microfluidic device of group II, as recited in claim 17, requires the incorporation of a capillary passageway and a metering capillary. Whereas, the microfluidic device of group III, as recited in claim 21, does not specifically require the incorporation of a capillary passageway and a metering capillary, but an adsorbent substrate strip. Therefore, the microfluidic device utilized in the invention of group II can function using a different mode of operation, which does not require an adsorbent substrate strip.

Inventions IV and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because, for example, the microfluidic device of group IV, as recited in claim 24, does not specifically require the incorporation of a capillary passageway and a metering capillary, as claimed for the microfluidic device of group II in claim 17, but an inlet passageway containing ridges or grooves disposed perpendicularly to the sample flow and wherein the passageway widens into a reagent chamber. The subcombination has separate utility, such as an analytical microfluidic device utilized in assays, in which the assays do not require that the microfluidic device comprise a capillary passageway and a metering capillary.

Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the

subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because, for example, the microfluidic device of group III, as recited in claim 21, does not require an inlet passageway containing ridges or grooves disposed perpendicularly to the sample flow and wherein the passageway widens into a reagent chamber, as claimed for the microfluidic device of claim 24. The subcombination has separate utility, such as an analytical microfluidic device utilized in assays, in which the assays do not require that the microfluidic device comprise an absorbent substrate strip.

Because these inventions are distinct for the reasons given above and the prior art searches for each of the groups are different, restriction for examination purposes as indicated is proper.

A telephone call was made to Elizabeth A. Levy on 11/18/2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

